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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,715	01/22/2004	Kristian DiMatteo	10123/03601	5203
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Patrick J. Fay, Esq. FAY KAPLUN & MARCIN, LLP Suite 702 150 Broadway New York, NY 10038				
EXAMINER				
GRAY, PHILLIP A				
ART UNIT		PAPER NUMBER		
3767				
MAIL DATE		DELIVERY MODE		
12/02/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/762,715

Applicant(s)

DIMATTEO ET AL.

Examiner

Phillip Gray

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-19 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-19 and 21-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This office action is in response to applicant's communication of 8/15/2008. Currently claims 1-5, 7-19, and 21-24 are pending and stand rejected below. This office action has been reopened to make new rejections. The finality of the last action is withdrawn.

Specification

The amendment filed 7/6/2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the added claim limitation of the catheter "to permit fluid to flow into the catheter without impinging on the valve".

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession

of the claimed invention. The "open a valve of the catheter to permit fluid to flow into the catheter **without impinging on the valve**" is not specifically described in the specification in a manner which to say what is meant, what is limited by the language, and how the device goes about this function. Examiner is unsure how this claim limitations relates to the applicant's invention or how the language in the claim limits or distinguishes it from the prior art. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7-8, 11-13, 18-19, 21, and 23 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Dryden (U.S. Patent 5,125,893).

Dryden discloses a catheter system with a connector for injecting fluid to a catheter (as in figure 1) comprising an attachment portion (near 27) to fluidly couple to a source of pressurized fluid (12 for example), an elongate tubular hypotube bypass element (element 31/28) adapted to open a valve (such as 23) of the catheter (such as system

11/17/22) to permit fluid to flow into the catheter without impinging on the valve (as described in columns 2-3, wherein the tubular bypass element has a diameter to fit in a flow opening of the valve) and an over pressure control element (35 or 36) which would be fully capable of being adapted to maintain a pressure of fluid within the connector below a predetermined threshold (as described in column 2 lines 45-56) and be a pressure relief valve. It is examiners position that an overpressure control element or "pressure relief valve" (as identified in applicant's claim 7) adapted to maintain a pressure of fluid within the connector below a predetermined threshold level is inherent in the Dryden reference (valve 35 i.e. and its function) but in the alternative it would have been an obvious modification thereof and well known to a person having ordinary skill in the art to construct the valve (35) to be an "over pressure control element" to allow a safe pressure level of fluid to reach a patient, and be a pressure relief valve. Such valves are well known in the art. For some information on possible over pressure valve types and teachings as to the benefits see Binard et al. (U.S. Patent 4,124,525 and paragraphs at columns 1-2 and column 4 lines 53-65 for examples). These types of pressure relief valves have controlled failure elements designed to fail when a fluid pressure level reached a threshold. It is examiners position that the bypass element is fully capable of being adapted to open a pressure actuated safety valve of a venous catheter, and that the attachment portion is fully capable of being adapted to connect to a contrast media power injection system. It has been held that the recitation that an element is "adapted to" to perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In*

re Hutchinson, 69 USPQ 138. The elements disclosed in Dryden are fully capable of satisfying all structural, functional, spatial, and operational limitations in the amended claims, as currently written, and the rejection is made and proper.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9-10, 22, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dryden in view of Campbell et al. (U.S. Patent Number 6,375,637).

Dryden discloses the claimed invention except for the overpressure control element being an extension tube and having a external collection jacket disposed

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around. Campbell teaches that it is known to use an overpressure control element being an extension tube and having a external collection jacket (Campbell 31) disposed around as set forth in paragraphs at columns 1-3 to provide a controlling means to prevent catastrophic failure of the device by controlling the pressure inside the catheter. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Dryden with an overpressure control element being an extension tube and having a external collection jacket disposed around as taught by Campbell, since such a modification would provide the system with the overpressure control element extension tube and an external collection jacket for providing a controlling means to prevent catastrophic failure of the device by controlling the pressure inside the catheter.

Claims 14 –17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dryden.

Dryden discloses the claimed invention except for the threshold level being approximately 300, 100, 80, or 40 p.s.i.. It would have been obvious to one having ordinary skill in the art at the time the invention was made for the threshold level to be approximately 300, 100, 80, or 40 p.s.i., since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (CCPA 1955), and since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571)272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phillip Gray/
Examiner, Art Unit 3767
/Kevin C. Simons/
Supervisory Patent Examiner, Art Unit 3767